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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/429,331	10/28/1999	LISA A. PAIGE	PAIGE=1D	5796

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/429,331	PAIGE ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-134 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-134 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29, 35-39, 43, 45-58, 70-72, 81, 83 and 99-101, drawn to a method of predicting the receptor-modulating activity of a compound.

II. Claims 30, 32-33 and 59-63, drawn to a peptide.

III. Claims 31, 42 and 64-69, drawn to a panel.

IV. Claims 34, 40-41, 44, 80, 82, 86-89 and 96-98 drawn to a non-naturally occurring peptide.

V. Claims 73-77, drawn to a method of antagonizing the activation of a nuclear receptor in a cell.

VI. Claim 78, drawn to a method of screening for an agonist of a receptor requiring a co-activator.

VII. Claim 79, drawn to a method of screening for ligands specifically to ER beta.

VIII. Claim 84, drawn to a method of identifying an oligomeric molecule which modulates G-protein coupled receptor, specific to the activation state of G-alpha subunit.

IX. Claim 85, drawn to a method of identifying an oligomeric molecule which modulates G-protein coupled receptor, indifferent to the activation state of G-alpha subunit.

X. Claims 90-95, drawn to a method of identifying a modulator of a GPCR comprising assaying potential modulators.

XI. Claims 102-117, drawn to a method of identifying a substance as an agonist or antagonist using reporter protein moiety.

XII. Claims 118-122, drawn to a method of identifying a substance as an agonist or antagonist of GPCR using donor fluorophore.

XIII. Claim 123, drawn to a method of identifying a substance as an agonist or antagonist of GPCR using G-alpha subunit in a fusion protein.

XIV. Claim 124, drawn to a method of identifying a substance as an agonist or antagonist of GPCR wherein the fusion protein comprising a peptide binds in an activation state-specific manner.

XV. Claim 125, drawn to a method of identifying a substance as an agonist or antagonist of GPCR using library of cells.

XVI. Claims 126-130, drawn to a known method of identifying a substance as an agonist or antagonist of GPCR with modifying step of expressing a chimeric.

XVII. Claim 131, drawn to a known method of identifying a substance as an agonist or antagonist of GPCR with modifying step of expressing a chimeric using a library of cells.

XVIII. Claim 132, drawn to an assay.

XIX. Claims 133-134, drawn to a method of determining whether a substance is an agonist or antagonist of a receptor where the co-activator of said receptor is unknown.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, V and VI-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to distinct methods wherein each contains different or additional steps and/or components with different functions and effects. For example, the method of Group I

recites for providing a panel of plurality of members to achieve the desired effect. Group XIX recites for determining whether a substance is an agonist or antagonist of a receptor using an unknown co-activator.

Inventions II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally different compounds i.e., peptides with motifs, without motifs and panel (plurality) of peptides with or without motifs.

Inventions II, III and IV and I, V and VI-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods and different compounds that are independent and distinct from one another in function, modes of operation, effects and structures.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search

required for Group I is not required for Group II-XIX, specifically the scientific literature journals that are not co-extensive with U.S. or foreign patents, restriction for examination purposes as indicated is proper.

Claims 1, 30, 31, 34, 73, 78, 79, 90, 102, 118, 123-127 and 133 are generic to a plurality of disclosed patentably distinct species comprising:

If Group I is elected, applicants are to elect ***one species*** from each of the following subgroups (for example, one from A, one from B and so forth) as follows:

A. Receptor (e.g., claims 8-10. Note while the termd species I used however, the claims are actually generic receptor. Thus an election of nuclear receptor is not a species election. Applicants are to elect a species of said nuclear receptor).

B. Ligand (e.g., claim 11. See note under A)

C. Reference Conformation species (e.g., as recited in claim 35)

D. Combinatorial library (i.e., oligopeptide or nucleic acid as recited in claims 14 or 15).

E. Test substances

F. Screening (e.g., in vitro, cell-based assay and etc. as recited in e.g., claims 18 and 19). If in vivo assay is elected,

elect a single assay system comprising of a specific component for the e.g., two-hybrid assy.

G. Reference substance as recited in e.g., claim 22.

H. Panel species (e.g., one class from table 3 or those representing the different classes as recited in e.g., claim 36) or one with or without a LXXL motif.

If Group II is elected, applicants are to elect ***one species*** as follows:

A. Peptide (i.e., one function), if a structure is present, one peptide with one structure).

If Group III is elected, applicants are to elect ***one species*** as follows:

A. See H above.

If Group IV is elected, applicants are to elect ***one species*** as follows:

A. Non-naturally occurring peptide i.e., only a single peptide with a ***single*** function.

If Group V is elected, applicants are to elect ***one species*** from the subgroups as follows:

A. Receptor, see as in above A

B. AF-2 mediated ER activity or not

If Group XI-XIV is elected, applicants are to elect ***one species*** from the following subgroups as follows:

A. Agonist or antagonist

B. T-peptide from table 202B

C. D-peptide from Table 202C

D. Reporter

E. Signal

F. Receptor

Each of the species in each of the subgroups e.g., A differs in structure and function as evident from the different functions, as claimed. Thus, a prior art reference anticipating one species would not render obvious the other species within each the subgroups.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be

examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on(571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
April 5, 2004